Docket No. 92077.003us3
Customer No. 75,004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	**Jacob Richter et al.**	**Confirmation No.:**	**1194**
Serial No.:	**09/864,389**	**Group Art Unit:**	**3773**
Filed:	**May 25, 2001**	**Examiner:**	**Bui, Vy Q.**

Title: **LONGITUDINALLY FLEXIBLE STENT**

APPEAL BRIEF UNDER 37 C.F.R. §41.37

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Further to the Notice of Appeal filed on August 12, 2009, and the Notice of Panel Decision from Pre-Appeal Brief Review dated October 9, 2009, applicant respectfully submits this appeal brief in accordance with 37 CFR 41.37. Favorable reconsideration and allowance of this application is respectfully requested in view of the following.

I. Real Party in Interest

The real party in interest is Medinol, Ltd., the assignee of record, which is a private company located in Israel.

II. Related Appeals and Interferences

Appellant identifies the following prior appeals, judicial proceedings or interferences known to the appellant which may be related to, directly affect or have a bearing on the Board's decision in the pending appeal:

- United States Patent Application No. 11/395,751
  Notice of Appeal filed on May 14, 2009 with Pre-Appeal Brief Request for Review; Notice of Panel Decision from Pre-Appeal Brief Review issued on August 5, 2009 withdrawing the Final Rejection

- United States Patent No. 6,723,119
  Notice of Appeal filed on June 3, 2003, followed by an Amendment After Final under 37 C.F.R. 1.116 on September 11, 2003.

III. Status of Claims

Claims 1, 3, 6, 8, 11, 26, 28, 42-47 and 49 have been rejected by the Examiner in the Final Rejection dated May 12, 2009. The Examiner has rejected claims 1, 6, 11, 26, and 42-47 as being anticipated under 35 U.S.C. § 102(e), or in the alternative, as obvious under 35 U.S.C. § 103(a) in view of U.S. Patent No. 7,204,848 (Brown et al). Further, the Examiner has rejected claims 3, 8 and 28 as obvious in view of U.S. Patent No. 6,776,793 (Brown et al) in view of U.S. Patent No. 6,120,847 (Yang et al), and claim 49 as being unpatentable as obvious under Brown '793 in view of U.S. Patent No. 6,179,868 (Burpee et al). Claims 1, 6, 42-44 and 49 are being appealed.

Claims 2-5, 7-41, and 45- 48 and 50-51[1] have been canceled. Claims 3, 8, 11, 26, 28 and 45-47 have been canceled solely to reduce the number of issues on appeal.

IV. Status of Amendments

Claim amendments have been submitted by applicant following the notice of appeal but prior to submitting the present Appeal Brief on December 8, 2009, pursuant to 37 CFR 1.116 and 41.33.

V. Summary of Claimed Subject Matter

V.A. Claim 1

Independent claim 1 recites a stent formed by first and second loop containing sections that are each joined directly, without intervening materials, to third loop containing sections occurring between each first and second loop containing section. Said loop containing sections are formed from single, continuous, sinusoidal patterns and include struts. The first and second loop containing sections extend around the entire circumference of the stent. The loops of the first and second loop containing sections occur at the same frequency, whereas the loops of the third loop containing sections occur at a higher frequency than the loops of the first and second loop containing sections. In addition, the struts of the first and second loop containing sections are wider than the struts of the third loop containing sections. Lastly, the loops in the first, second and third loop containing sections cooperate such that the loops of

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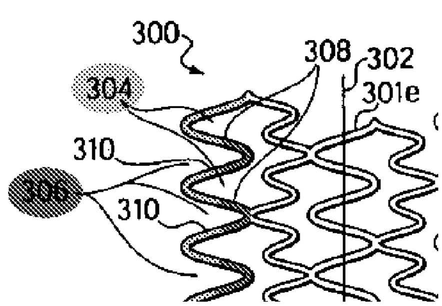
[1] Applicants note that claims 50-51, which were inadvertently omitted from the list of claims last reviewed by the Examiner, were originally added by applicants in claim amendments submitted on October 18, 2004 and were subsequently cancelled in claim amendments submitted on May 25, 2005.

the third loop containing section contribute to the elongating or shortening of the stent when flexed.

The specification[2] describes the arrangement of “first”, “second” and “third loop containing sections” in paragraph [0050] with reference to Figures 3 and 5. As indicated in paragraph [0050], the specification refers interchangeably to “vertical loop containing sections” and “vertical sinusoidal patterns.” Thus, the description of a “vertical sinusoid” in paragraph [0039] of the specification also applies to “loop containing section”, as that term is used in claim 1. Paragraph [0039] describes a “vertical sinusoid” / “loop containing section” as “a periodic pattern which varies positively and negatively symmetrically about an axis” such that a right-opening loop 304 is joined to a left-opening loop 306 with a common member 310 between them, followed by another right-opening loop 304 also joined by a common member 310. In other words, a “loop containing section” is formed by a repeating sequence of loops 304 opening “to the right” that are each joined to loops 306 opening “to the left”, alternating along a circumferential axis as illustrated in Figure 3, shown below:



[2] All references to the specification refer to publication no. US 2002/0022876 A1.

The description of a “loop containing section” in paragraphs [0039] and [0050] therefore corresponds with the language recited by claim 1 that a “loop containing section” is formed of a “single, continuous, generally sinusoidal pattern.”

The specification further describes “first”, “second” and “third loop containing sections” with reference to axis lines 302 and 305 in paragraph [0050] as illustrated in Figure 3, shown below:

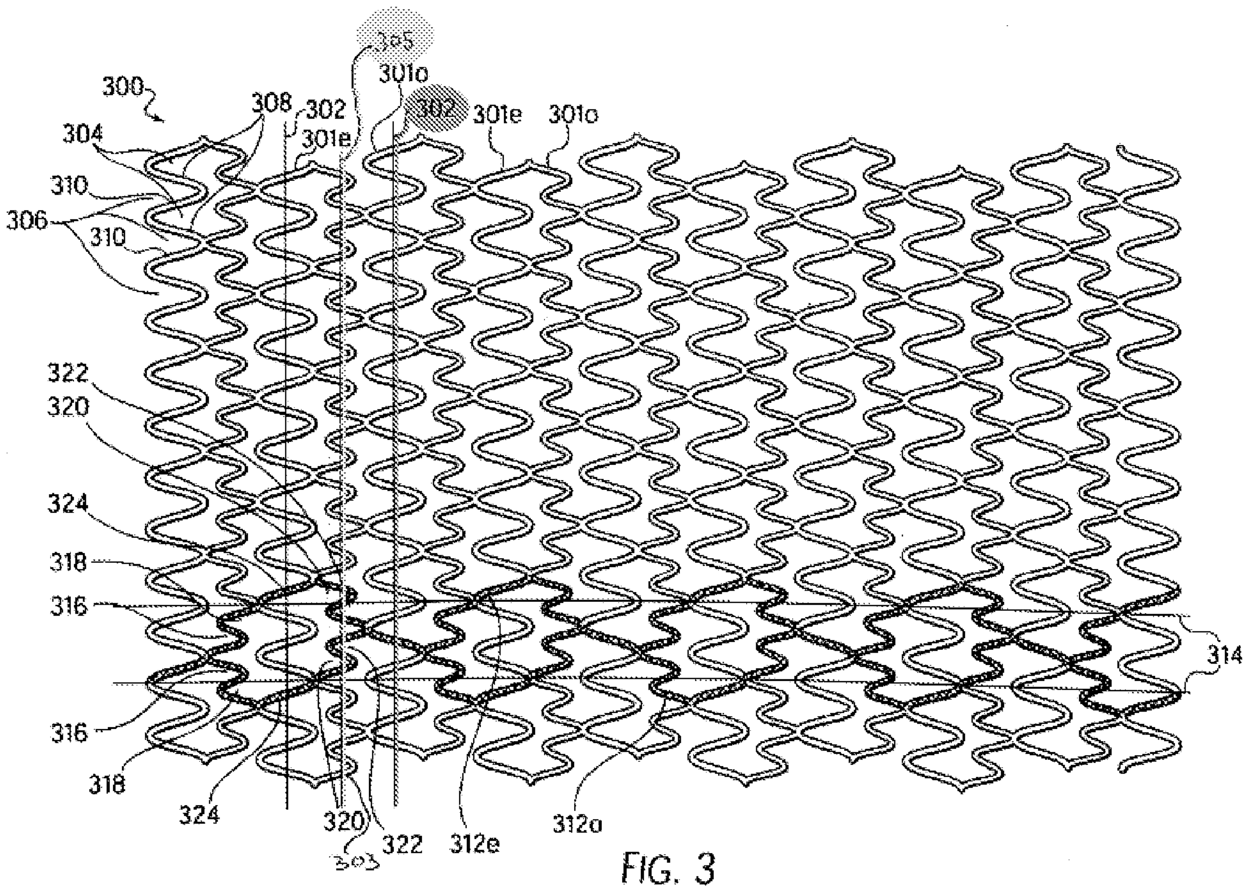


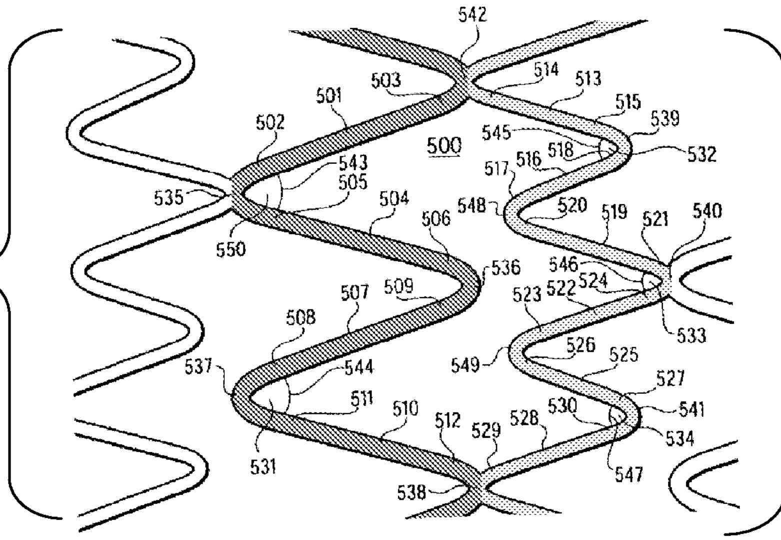
FIG. 3

Thus, for example, a second loop containing section occurs as a periodic pattern varying positively and negatively about an axis 302 (orange), while a third loop containing section occurs as a periodic pattern varying positively and negatively about an axis 305 (blue). Notably, the circumferential axes 302 and 305 extend along the

entire circumferential length of the stent; thus, as depicted in linear form by Figure 3, the loop containing sections are understood by one skilled in the art to extend around the entire circumference of the stent once formed. As illustrated in Figure 3 and described in paragraph [0050], the third loop containing section formed along axis 305 has loops that occur at a higher frequency than the loops of the second loop containing section formed along axis 302.

With regard to the contribution of the third loop containing sections to the elongating and shortening of the cells when the stent is flexed, the specification describes the cooperation between elements of the stent in paragraphs [0048] and [0054] – [0055]. In paragraph [0048], the specification describes "fifth, sixth, seventh, eighth, ninth, and tenth members" with reference to Figure 4 that are "optimized predominantly to enable longitudinal flexibility" relative to "first, second, third, and fourth members", which by contrast are "optimized predominantly to enable sufficient resistance to radial compression." As noted in paragraph [0046], Figure 4 is an "expanded view" of the stent illustrated in Figure 3, and one skilled in the art will recognize in Figure 4 the fifth, sixth, seventh, eighth, ninth, and tenth members make up the higher-frequency "third loop containing sections" and the first, second, third, and fourth members make up the lower-frequency "first" and "second loop containing sections" wherein these latter loop containing sections have struts of greater width, as shown below:

First (501), second (504), third (507) and fourth (510). members corresponding to a low frequency loop containing section.



Fifth (513), sixth (516), seventh (519), eighth (522), ninth (525) and tenth (528) members corresponding to a high frequency loop containing section.

FIG. 4

Thus, the application contemplates higher frequency third loop containing sections (blue) contributing to the overall flexibility of the stent relative to the first and second loop containing sections (orange), which by comparison provide radial strength to the stent. The contribution of third loop containing sections upon flexing of the stent is further described by the specification at paragraphs [0054] – [0055] with reference to Figure 15 as shown below:

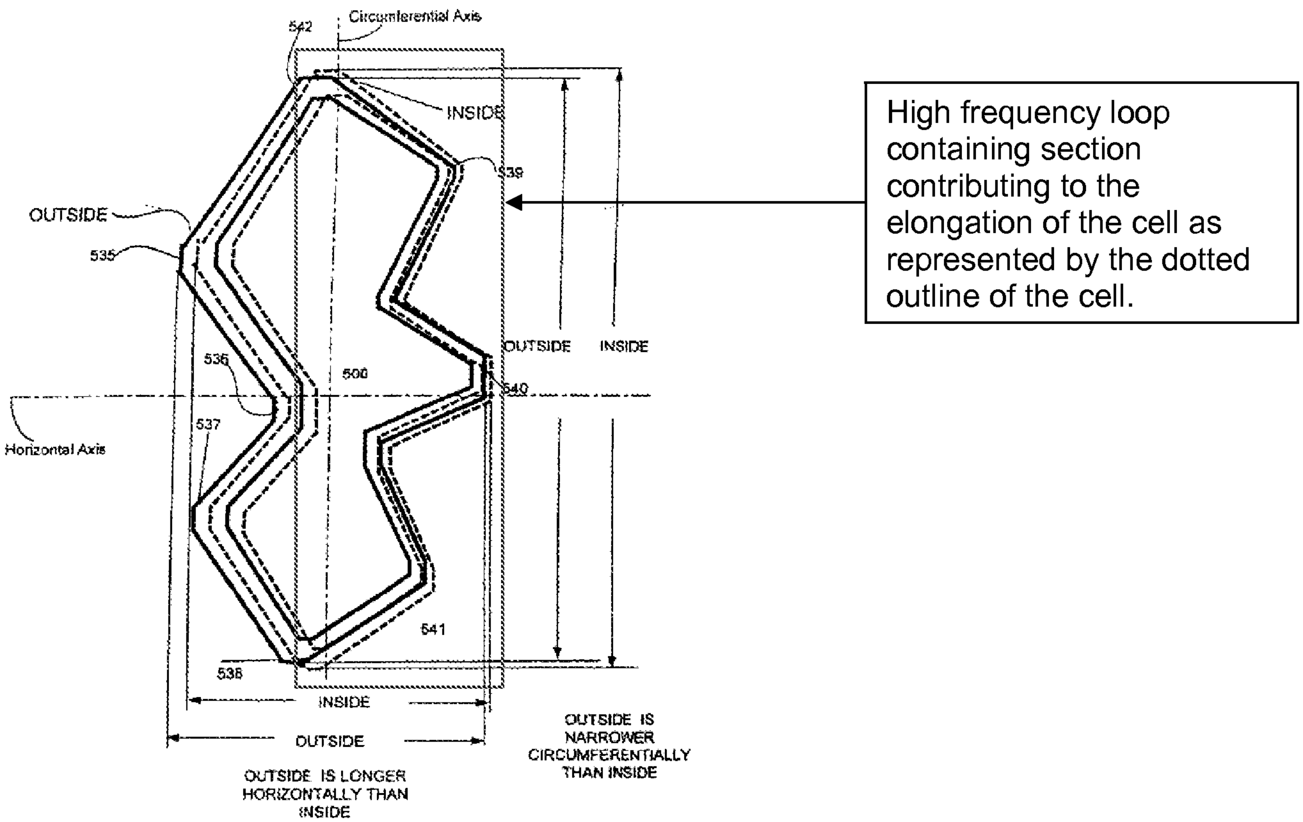
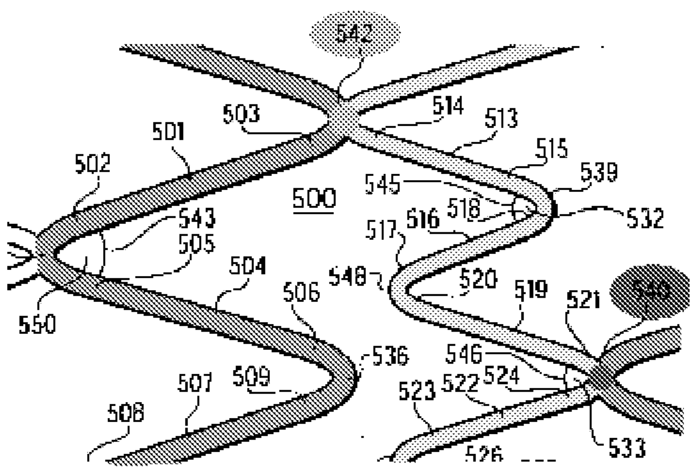


Figure 15 indicates the deformation of the cell following the flexing of the stent by dotted outline, such that the high frequency loop containing section deforms to elongate the cell. Thus, as recited by claim 1, the specification contemplates components of the high frequency third loop containing section contribute to the elongating or shortening of the stent when flexed.

Further, as noted by the specification in paragraph [0050], “the higher frequency loop containing elements are smaller in width.” As discussed in paragraph [0051], the novel feature of “high frequency vertical patterns of smaller width” results in elements of the stent having a lower maximal strain without non-elastic deformation. The application specifically identifies the smaller width in the high frequency bands as advantageous for increased flexibility of the invented stent, aiding both in “conforming

better to the curved lumen" as well as "bend[ing] with each beat of the heart . . . for many years without breaking."

With regards to the limitation recited in claim 1 that the third loop containing section is connected directly "without intervening materials" to the first and second loop containing sections, the specification in paragraph [0046] clearly identifies "junction point[s]" 540 and 542 with regard to Figure 4 – which, as noted above, provides an "expanded view" of the stent illustrated by stent 3 -- where a higher frequency loop containing section connects directly to a lower frequency loop containing section, as shown below:



Thus, "junction point" 540 (red) and "junction point" 542 (green) represent the points at which a higher-frequency "third loop containing section" connects directly to a lower-frequency "first or second loop containing section" without intervening material.

Accordingly, the limitations recited by claim 1 correspond with the stent depicted by Figure 3 and described throughout the specification.

V.B. Claim 6

Independent claim 6 recites a stent formed by first and second circumferential bands, each formed of a single, continuous, generally sinusoidal pattern of loops extending around the entire circumference of the stent. The first and second circumferential bands alternate along the longitudinal axis of the stent for at least two repetitions and are periodically coupled directly without intervening materials to form cells. The loops of the second circumferential bands occur at a higher frequency than the loops of the first circumferential band, and the loops of the first circumferential band have struts that are wider than the struts of the loops of the second circumferential band. The loops of the first and second circumferential bands are disposed and adapted to cooperate so that the second circumferential band contributes more to deformation during flexing than the first circumferential band.

One skilled in the art will recognize that a “circumferential band”, particularly as described by claim 6 as a “single, continuous, generally sinusoidal pattern of loops”, corresponds with the “vertical sinusoid” disclosed in the specification in paragraphs [0039] and [0050], as discussed above. Furthermore, Figure 3 clearly illustrates the stent as recited by claim 6, wherein first circumferential bands having loops occurring at a lower frequency alternate with second circumferential bands having loops occurring at a higher frequency, wherein the first circumferential bands are coupled directly to second circumferential bands without intervening materials to form cells, as shown below:

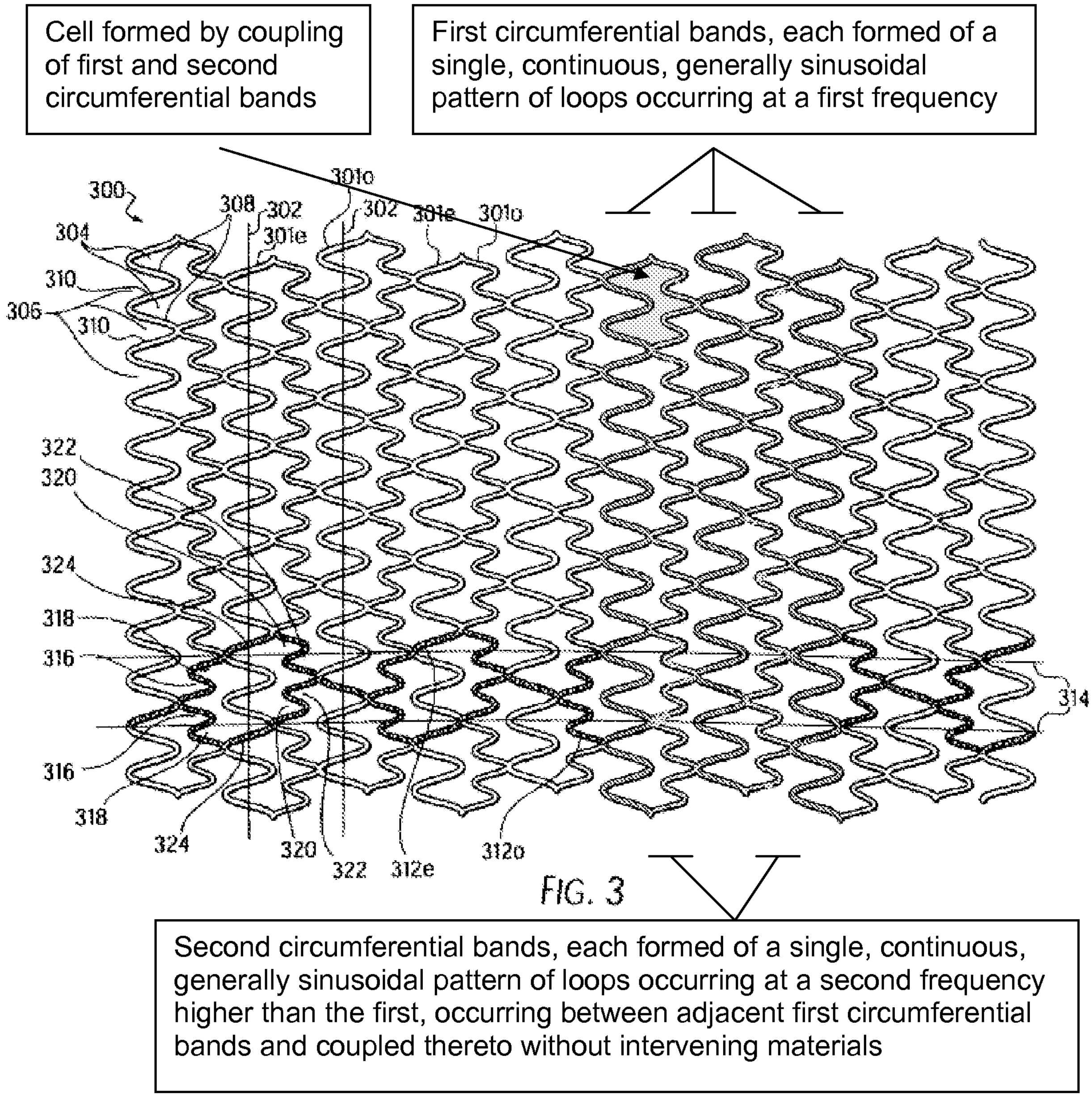


FIG. 3

Thus, as illustrated in Figure 3, the application discloses a stent formed by first circumferential bands (orange) coupled directly with second circumferential bands (blue) without intervening materials, wherein the first and second circumferential bands are each formed of a single, continuous, generally sinusoidal pattern of loops, as recited by claim 6.

With regard to the relative contribution of the second circumferential bands to deformation during flexing of the stent, the specification describes the cooperation between elements of the stent in paragraphs [0048] and [0054] – [0055]. Therein, the application contemplates high frequency second circumferential bands having greater flexibility relative to the low frequency first circumferential bands. For example, in paragraph [0048], the specification describes “fifth, sixth, seventh, eighth, ninth, and tenth members” with reference to Figure 4 that are “optimized predominantly to enable longitudinal flexibility” relative to “first, second, third, and fourth members”, which by contrast are “optimized predominantly to enable sufficient resistance to radial compression.” As noted in paragraph [0046], Figure 4 is an “expanded view” of the stent illustrated in Figure 3, and one skilled in the art will recognize that the fifth, sixth, seventh, eighth, ninth, and tenth members correspond to a second circumferential band while the first, second, third, and fourth members correspond to a first circumferential band. Further, at paragraphs [0054] – [0055] with reference to Figure 15, the specification describes the behavior of a cell when the stent is flexed. As shown above, the high frequency band of loops naturally deforms due to its relatively greater flexibility when the stent is flexed. Thus, as recited by claim 6, the specification contemplates high frequency circumferential bands of loops having relatively greater flexibility and thereby contributing more than the low frequency circumferential bands to the deformation of the stent when flexed.

Lastly, as noted by the specification in paragraph [0050], “the higher frequency loop containing elements are smaller in width.” In the context of claim 6, the “higher frequency loop containing elements” correspond with second circumferential bands,

with lower frequency loop containing elements corresponding to first circumferential bands. The specification therefore describes first circumferential bands having struts that are wider than the struts of the second circumferential bands as recited by claim 6.

Accordingly, the limitations recited by claim 6 correspond with the stent depicted by Figure 3 and described throughout the specification.

V.C. Claim 49

Independent claim 49 recites a stent consisting essentially of first and second loop containing sections, each having loops occurring at the same frequency with the loops of the second loop containing sections being 180º out of phase with the loops of the first loop containing sections, and a third loop containing section having loops occurring at a higher frequency than the loops of the first and second loop containing sections. At least one of the first and second loop containing sections as well as the third loop containing sections are formed of a single, continuous, generally sinusoidal pattern of loops. The third loop containing sections are disposed between each of the first and second loop containing sections to form a consecutively repeating pattern for at least two repetitions. Further, the third loop containing sections are joined alternately to the first and second loop containing sections forming a pattern of uniform cells. Finally, the first, second and third loop containing sections have struts, wherein the struts of the first and second loop containing sections are wider than the struts of the third loop containing sections.

The understanding of a "first", "second", and "third loop containing section" is described in detail in section V.A. Of note, claim 49 recites a stent consisting essentially of said first, second and third loop containing sections wherein at least one of the first or second loop containing sections are single, continuous and generally sinusoidal, and the third loop containing section is also single, continuous and generally sinusoidal as shown below in Figure 3:

First loop containing sections formed of a single, continuous and generally sinusoidal pattern.

Second loop containing section also formed of a single, continuous and generally sinusoidal pattern and having loops that are 180° out-of-phase with the loops of the first loop containing sections.

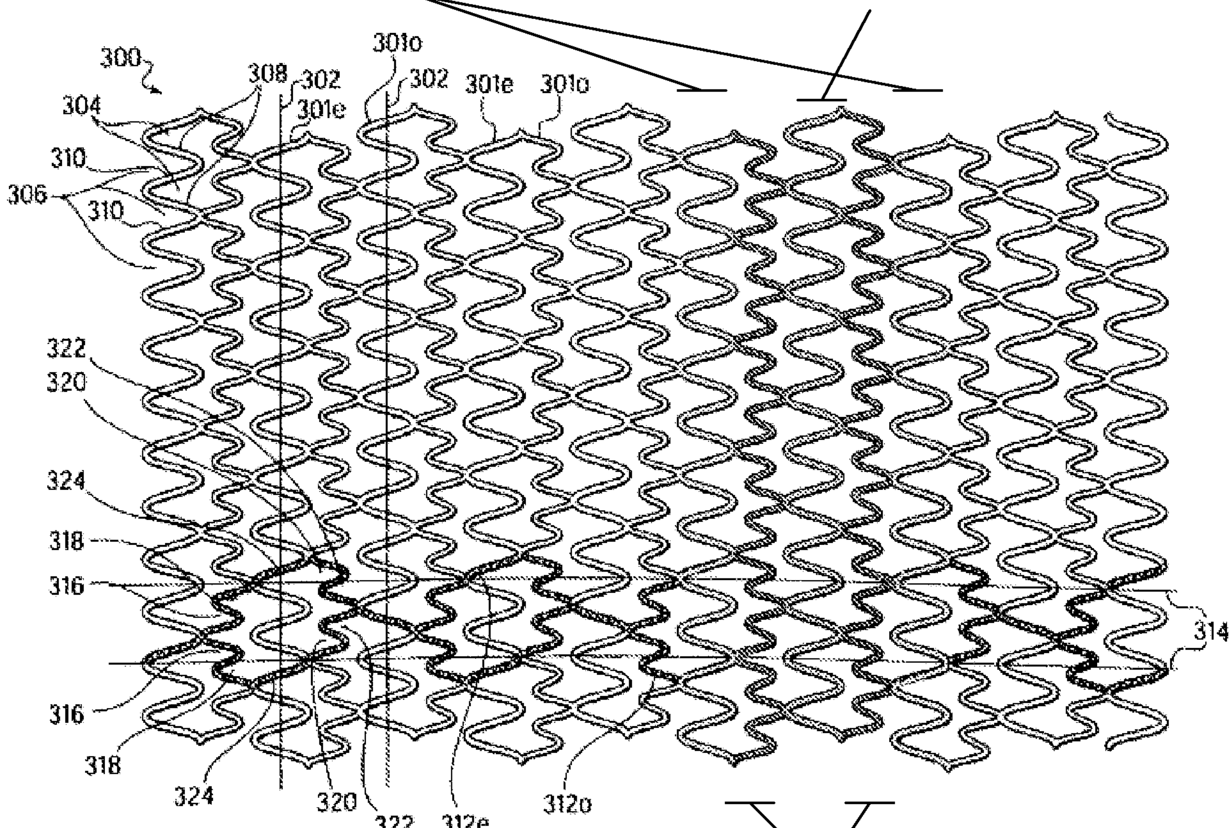


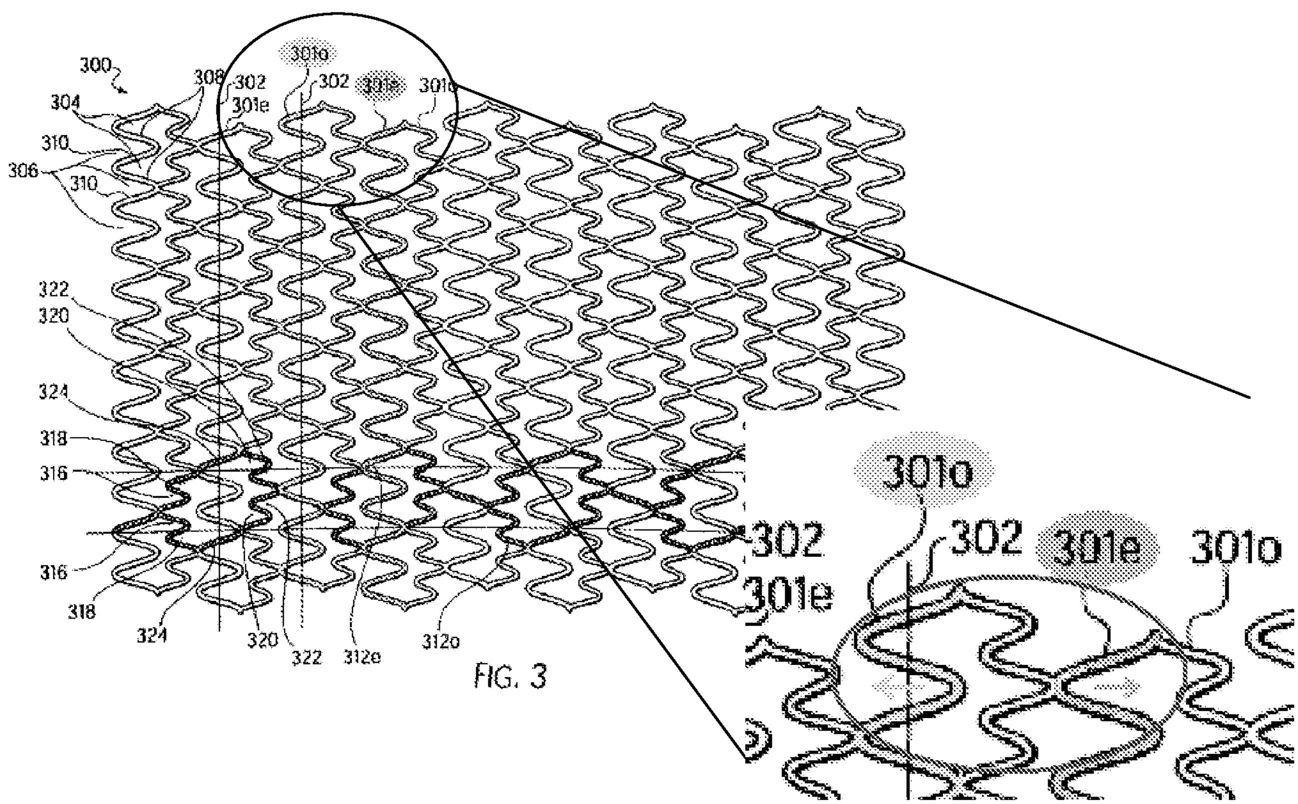
FIG. 3

Third loop containing sections, each formed of a single, continuous and generally sinusoidal pattern, disposed in the generally circumferential space between each first and second loop containing sections to form a pattern along the longitudinal axis of the stent.

As is well understood, “consisting essentially of” limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. In re Herz, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) (emphasis in original); see also MPEP §2111.03. Therefore, insofar as the third loop containing section must be a single, continuous, generally sinusoidal pattern of loops, and further occurs between each of the first and second loop containing sections (at least one of which must also be a single, continuous, generally sinusoidal pattern of loops) and connects together with them to form a uniform pattern of cells, there necessarily is no intervening material between the third loop containing section and either the first or the second loop containing sections, as this would necessarily affect the basic and novel characteristics of the claimed stent (as discussed in more detail in section VII.G, infra). Likewise, the placement of high frequency third loop containing sections between first and second loop containing sections – said first and second loop containing sections having struts that are wider than the struts of the third loop containing section – contributes to the basic and novel characteristics of the stent in that, as taught by the present application, e.g. paragraph [0051], the third loop containing sections contribute to overall flexibility whereas the first and second loop containing sections provide increased radial resistance. One skilled in the art will recognize the advantage to having low frequency loop containing sections having increased radial resistance at either end of the stent (as well as located throughout the middle of the stent) with high frequency loop containing sections having increased flexibility there between. The low frequency loop containing sections having wider and longer struts are ideally suited to provide radial strength. The high frequency

loop containing sections are suited for flexibility because the higher number of loops provides that each loop has a lower maximal strain allowing for long-term bending without breakage.

Finally, with regard to the limitation recited in claim 49 that the loops of the second loop containing section are 180° out of phase with the loops of the first loop containing section, paragraph [0041] specifically references vertical meander patterns – understood by one skilled in the art as synonymous with "loop containing sections" (see paragraph [0050]), as discussed above – "in odd and even (*o* and *e*) versions which are 180° out of phase with each other" with reference to Figure 3. As shown below, Figure 3 clearly illustrates first and second loop containing sections, in which an adjacent second loop containing section has loops that are 180° out of phase with the loops of a first loop containing section.



Thus, as described in paragraph [0041] and illustrated in Figure 3, claim 49 recites a first loop containing section 301o (blue) adjacent a second loop containing section (301e) having loops which are 180º out of phase with each other.

Accordingly, the limitations recited by claim 49 correspond with the stent depicted by Figure 3 and described throughout the specification.

VI. Grounds of Rejection to be Reviewed on Appeal

- Whether claims 1, 6 and 42-44 are unpatentable under 35 U.S.C. § 102(e) in view of Brown '848.
- Whether claims 1, 6 and 42-44 are unpatentable under 35 U.S.C. § 103(a) in view of Brown '848.
- Whether claim 49 is unpatentable under 35 U.S.C. § 103(a) over Brown '793 and Burpee.

VII. Argument

VII.A. Claim 1 is patentable pursuant to 35 U.S.C. § 102(e) in view of Brown '848

1. Claim 1 has been rejected pursuant to 35 U.S.C. § 102(e) on the basis that Brown '848 allegedly describes adjacent first, second and third loop containing sections that are "directly joined" to one another. Applicant respectfully disagrees with this rejection.

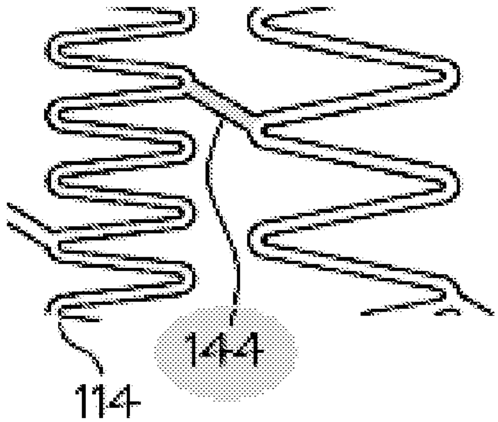
The Examiner identifies structures he refers to as first, second and third loop containing sections described by Brown to be "single, continuous, [and] generally

sinusoidal", noting that the loop containing sections "are single because they have single members, such as members 120 or 144." Applicants respectfully disagree with the Examiner's characterization of Brown '848. As explained below, Brown '848 explicitly teaches away from the stent recited by claim 1 and therefore cannot anticipate claim 1 under 35 U.S.C. § 102(e).

As an initial matter, the term "single" refers to the "pattern" not the "members" as recited in claim 1. It is therefore irrelevant whether the alleged first, second and third loop containing sections that the Examiner identifies "have single members". Rather, the pertinent inquiry is whether the members form a single, continuous and generally sinusoidal pattern of loops.

The Brown '848 reference generally addresses the problem of "binding, overlapping or interference [that] can occur between adjacent segments" in an articulated stent (1:56-2:3). Under the stated goal of "provid[ing] a flexible stent formed of interconnected bands" which "avoids the problem of pinching or overlap between adjacent bands", Brown '848 describes a stent comprising "interconnected band-like elements characterized by alternating peaks and troughs", alternatively described as "undulating band-like elements of a selected wavelength or wavelengths", and "further compris[ing] a plurality of interconnecting elements having first ends and second ends", which "extend from adjacent band-like elements" (2:15-55). Thus, from the Summary onward, Brown '848 defines the stent as having two distinct structural elements, i.e. the "band-like elements" on the one hand and the "interconnecting elements" on the other hand. In fact, Brown '848 requires that "a minimum of one connecting element is required to join adjacent band-like elements" (6:6-7).

Brown '848 describes the "interconnecting elements" as "having first ends and second ends" that "extend from adjacent band like elements" (2:45-49), as shown in Figure 2 as follows:



In the context of Brown '848, interconnecting element 144 (blue) addresses the problem of binding, overlapping or interfering adjacent band-like elements by joining adjacent bands at "circumferentially offset and ... longitudinally offset" ends (2:31-33, 6:60-63). Thus, Brown '848 teaches away from a stent having adjacent band-like elements that connect directly to one another, opting instead to employ interconnecting elements to ensure that adjacent band-like elements <u>do</u> <u>not</u> <u>interact</u> with one another.

By contrast, the stent of claim 1 overcomes the problem addressed by Brown '848 through a new and inventive stent design, avoiding the problem of binding, overlapping or interference between loop containing sections without resorting to intervening materials such as the interconnecting members required by Brown '848. The Examiner alleges that Brown '848 nonetheless anticipates claim 1 by employing an expanded definition of a "loop containing section" without support either in the present application or in Brown '848. As shown below, the Examiner erroneously identifies a

"loop containing section" in Figure 2 of Brown '848 as including not only "single, continuous, generally sinusoidal pattern of loops around the entire circumference of the stent," as claimed (or "continuous waves" characterized by "a plurality of peaks" and "troughs" as described by Brown '848 (5:38-46)), but also includes "a plurality of interconnecting elements" (separately identified by Brown '848 (5:60-63)):

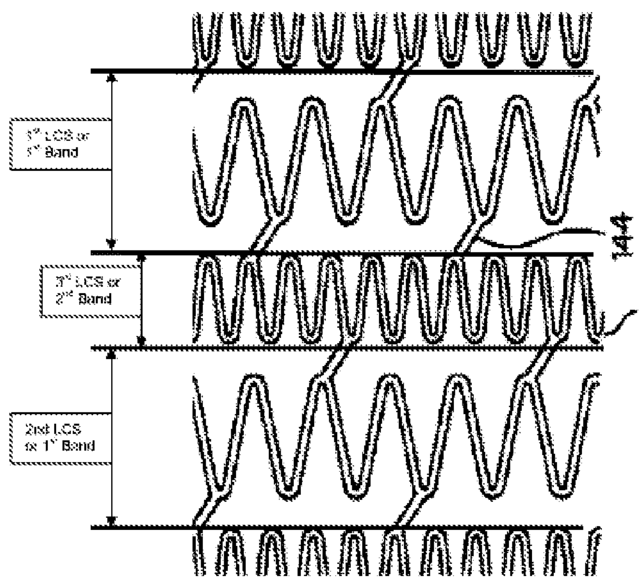


FIG. 2

The Examiner does not provide any support or reasoning for the inclusion of the Brown interconnecting elements 144 within the concept of first loop containing section as claimed. Moreover, the Examiner ignores entirely the stated problem addressed by Brown '848, i.e. the tendency of adjacent band-like elements to bind, overlap or interfere with one another when no circumferentially offset interconnecting elements are positioned to hold the band-like elements apart.

The Examiner's clear misunderstanding of the teachings of Brown '848 is evident in his reference to "members 120 or 144", which he characterizes as "loop containing sections or bands" each "hav[ing] single members." Whatever the Examiner meant by

“single members”, he has equated two structural elements that Brown ‘848 clearly differentiates as shown below in Figure 2.

“Band-like element” 120; see Brown ‘848, 5:37-46: “The configuration can be seen in these Figures to be made up of one or more spaced first band-like elements **120**. First band-like elements have a generally serpentine configuration to provide continuous waves to the first band-like elements.”

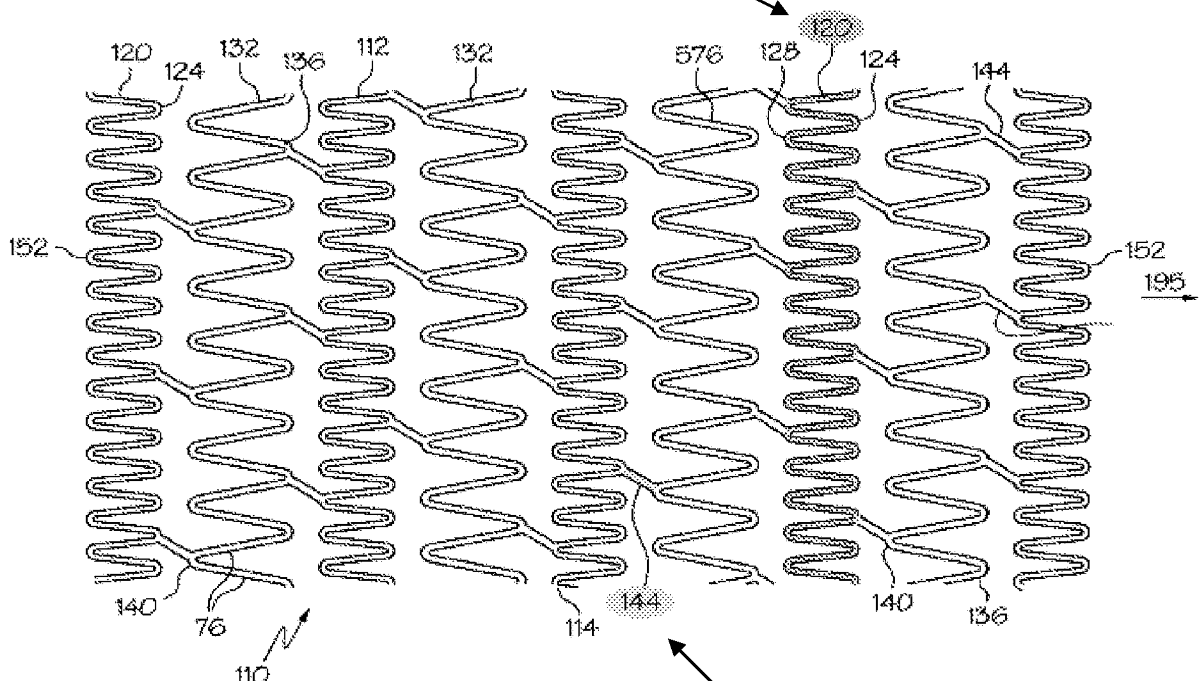


FIG. 2

“Interconnecting element” 144; see Brown ‘848, 5:60-63: “Adjacent first band-like elements **120** and second band-like elements **132** are interconnected via a plurality of interconnecting elements **144**. The ends of interconnecting elements are circumferentially offset from each other.”

Whereas element 120 (green) refers to a “first band-like element”, i.e. a continuous wave characterized by a plurality of peaks and troughs, element 144 (blue) refers to an “interconnecting element”, i.e. characterized by a first end and a second end extending between a peak and a trough of adjacent band-like elements”. One skilled in the art

reading Brown ‘848 would not recognize element 144 to include an adjacent band-like element to form a “generally sinusoidal loop containing section[]”.

Nowhere does Brown ‘848 teach or suggest a stent comprising a first, second and third loop containing section wherein the third loop containing section is joined to adjacent first and second loop containing sections directly without intervening material. Therefore, claim 1 is patentable over the Brown ‘848 reference.

2. In addition, Brown ‘848 does not teach or suggest “first”, “second” and “third loop containing section” having struts “wherein the struts of the first and second loop containing sections are wider than the width of the struts of the third loop containing section” as recited by claim 1. Brown does not teach or suggest a stent wherein the third loop containing section (i.e. the high frequency rings) “contribute to the cell’s elongating or shortening when the stent is flexed.” In fact, Brown’s stent results in the opposite effect, i.e., long strut rings perform this function as detailed below.

As noted in the present application, the width of the struts that form a stent impacts “the overall flexibility and resistance to radial compression” of the stent, such that thinner struts “enable longitudinal flexibility” while wider struts by comparison will “enable . . . resistance to radial compression” (paragraph [0048]). Notably, the figures of the present application illustrate that the lower frequency loop containing sections have wider struts at the ends of the stent. One skilled in the art will recognize the need for greater radial compression at the ends of the stent. Moreover, as discussed above with reference to paragraph [0051], the present application recognizes the structural advantage to forming high frequency loop containing sections with struts of smaller width. Specifically, the smaller width results in “elements having a lower maximal

strain", which provides increased flexibility of the stent to conform better to a curved lumen as well as bend with each beat of the heart for years without breaking.

Brown '848 contemplates a stent having struts of uniform width. Specifically, Brown '848 describes the stent illustrated by Figure 15 as having segments with "longer struts" that nevertheless exhibit "less compression resistance" than the shorter struts of the same stent (11:56-63). This passage teaches that rings having long struts in Brown '848 stents will have lower radial strength (i.e., lesser compression resistance) than the rings having short struts. Put yet another way, the short-strut rings of Brown '848 will provide the radial strength for the Brown stent and therefore be less flexible than the long strut rings. One skilled in the art will recognize that the employment of lower frequency bands to provide flexibility will result in a greater maximal strain – and therefore a higher likelihood that the stent will break with repetitive bends – due to the fact that the lower frequency bands have less loops per band. In contrast, claim 1 recites that the third loop containing sections (the high frequency rings) contribute to flexing, i.e., are more flexible than the first and second loop containing sections (the low frequency rings), thereby providing a lower maximal strain given the greater number of loops per band. Brown does not teach or suggest this inventive concept. Indeed, Brown contemplates varying "compression resistance" by adjusting the length of the struts, not the width, which results in the opposite structure (long struts) for the function to be achieved (flexibility).

Therefore, claim 1 is patentable over the Brown '848 reference.

VII.B. Claim 1 is patentable pursuant to 35 U.S.C. § 103(a) in view of Brown '848

1. Claim 1 has been rejected as obvious over Brown '848 on the alleged basis that "it would have been obvious to one of ordinary skill in the art to provide wider members 144 of 1st and 2nd loop containing sections in comparison to narrow members 120 of 3rd loop containing section" in accordance with the recitation of claim 1. Applicant respectfully disagrees with this rejection.

Although the Examiner does not elaborate, the Examiner recognizes the deficiency in Brown '848, i.e., that Brown '848 does not teach or suggest struts of a first and second loop containing section that are wider than struts of a third loop containing section as recited by claim 1. As discussed above, Brown '848 does not teach or suggest a stent having struts of varying widths.

Whereas the present application recognizes the benefit of varying the width of struts to achieve either longitudinal flexibility or, alternatively, resistance to radial compression (see paragraph [0048]), Brown '848 adjusts the length of struts in the "band-like elements" to vary "compression resistance." . Brown '848 identifies the length of a strut as the determinative factor (see 11:56-63), while completely ignoring the relative width of the different struts that form the stent. As such, the short-strut rings of Brown will be less flexible but provide more radial strength for the stent. As illustrated below in Figure 3, the short-strut rings will have higher compression resistance as required by Brown '848 simply by virtue of the fact that these rings contain more metal per area.

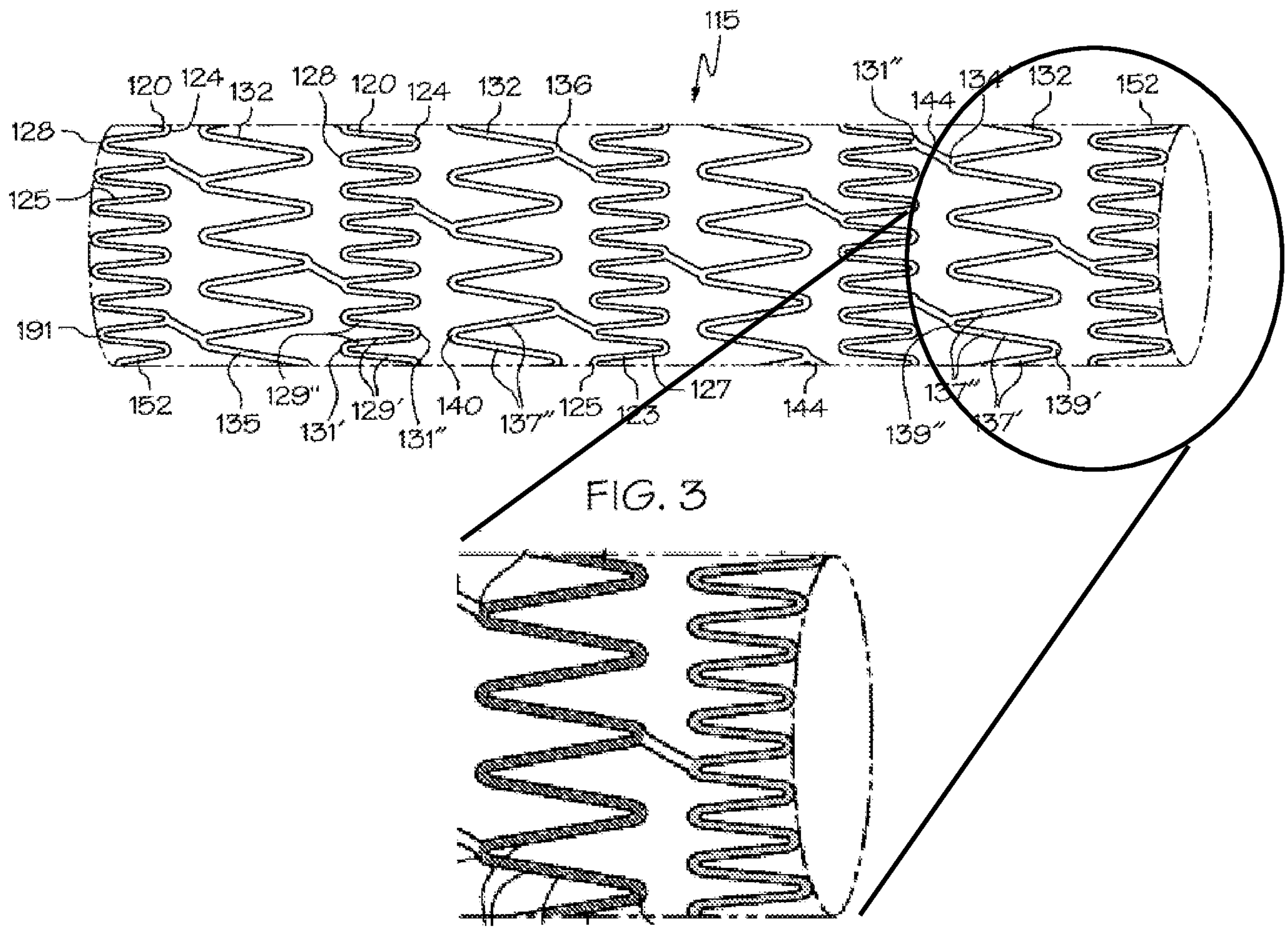


FIG. 3

The short-strut band-like element (green) of Brown clearly provide for more metal per area than the long-strut band-like elements (red), thereby necessarily providing greater resistance to radial compression as would be expected by one skilled in the art. In contrast, the stent of claim 1 relies on the short-strut (i.e., high frequency) rings to provide flexibility, while the long-strut (i.e., low frequency) rings provide resistance to radial compression. Moreover, as discussed above, paragraph [0051] of the present application specifically describes the benefit of having high frequency bands having struts of smaller width. Specifically, the greater number of loops per band combined with struts of a smaller width results in a lower maximal strain and increased flexibility to

better conform to a curved lumen and bend with each beat of the heart, whereas one skilled in the art will recognize that the employment of low frequency bands to provide flexibility results in a higher maximal strain given the lower number of loops per band, resulting in a stent more likely to break upon repeated bending. Therefore, Brown '848 does not render claim 1 obvious, but rather leads the skilled person away from the claimed invention.

Lastly, as discussed above, Brown '848 fails to teach or suggest a stent comprising third loop containing sections joined directly to first and second loop containing sections directly without intervening materials. The modification of the dimensions of members 144 relative to members 120 does not cure this deficiency.

For all the above reasons, claim 1 is patentable over the Brown '848 reference.

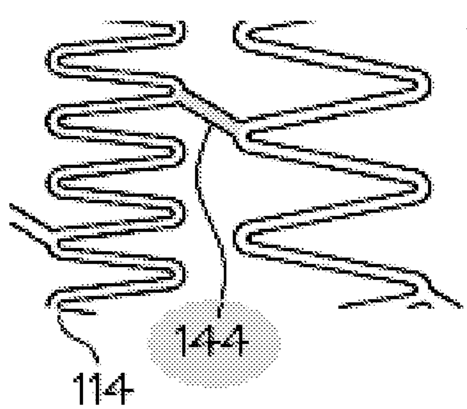
VII.C. Claim 6 is patentable pursuant to 35 U.S.C. § 102(e) in view of Brown '848

1. Claim 6 has been rejected pursuant to 35 U.S.C. § 102(e) on the basis that Brown '848 allegedly describes adjacent first and second bands that are "directly joined" to one another. Applicant respectfully disagrees with this rejection.

Claim 6 recites a stent having first and second circumferential bands, each formed of a single, continuous and generally sinusoidal pattern of loops. The Examiner fails to recognize that the terms of the claim, i.e. "single" and "continuous", exclude a structure having projections from the undulating bands. The claim additionally requires that the bands are "directly . . . coupled . . . without intervening material", again excluding the subject matter of Brown '848. Even the Brown '848 reference

distinguishes between "band-like elements" (e.g. element 120) and "interconnecting members" (i.e. element 144 of Figure 2). The Brown '848 reference describes each of these elements separately, for example at 5:37-59 (discussing "first" and "second band-like elements") and 5:60-63 (discussing "interconnecting elements" that join the "first" and "second band-like elements"). In contrast to the limitation recited in claim 6 that "second bands [are] periodically coupled to . . . first bands directly without any intervening materials", Brown '848 explicitly requires that "a minimum of one connecting element" joins "adjacent band-like elements" (6:6-8).

As discussed above, Brown '848 employs interconnecting elements in order to address the problem of binding, overlapping and interference between adjacent band-like elements (1:56-2:3). In accordance with that goal, the interconnecting elements taught by Brown '848 are characterized as "having first ends and second ends . . . extend[ing] from adjacent band-like elements" (2:15-55). Brown '848 further describes the interconnect elements as "circumferentially offset and . . . longitudinally offset" (2:31-33, 6:60-63). The description clearly matches element 144 of Figure 2 of Brown '848, as shown below:



Thus, Brown ‘848 explicitly teaches away from a stent in which a first band-like element, or circumferential band, connects directly with an adjacent second band-like element, or circumferential band without intervening material.

The Examiner incorrectly considers element 144 (blue) as a first circumferential band, notwithstanding the explicit disclosures of Brown ‘848 describing interconnecting element 144 as a separate and distinguishable element from the adjacent “first band-like elements 120 and second band-like elements 132”, which the interconnecting element 144 joins together as shown below.

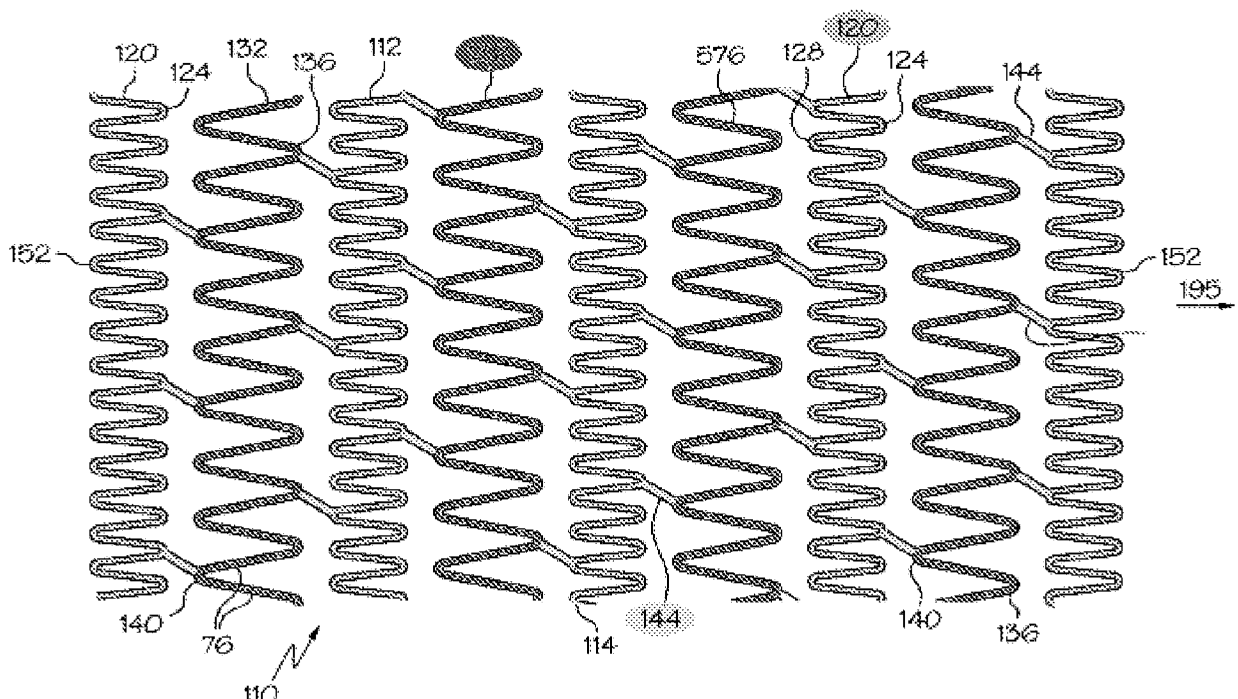


FIG. 2

The Examiner’s identification of a “first circumferential band” that incorporates the jutting interconnecting members 144 (blue) conflicts with both the limitation recited by claim 6 that the first circumferential bands are “formed of a single, continuous, generally sinusoidal pattern of loops” (see also paragraph [0039]) as well as the description in

Brown ‘848 of the “band-like elements”, e.g. elements 132 (red) and 120 (green), as “continuous waves” characterized by “a plurality of peaks” and “troughs” (5:38-46).

Nowhere does Brown ‘848 teach or suggest a stent comprising alternating first and second circumferential bands that are joined together directly without intervening material. Therefore, claim 6 is patentable over the Brown ‘848 reference.

2. In addition, Brown ‘848 does not teach or suggest “first” and “second circumferential bands” having struts “wherein the struts of the first bands are wider than the width of the struts of the second bands” as recited by claim 6. As discussed above, Brown ‘848 describes the functional significance of having stent struts of different lengths, while ignoring the relative widths of the struts. By contrast, claim 6 recognizes the benefit of varying the width of struts to achieve either longitudinal flexibility or, alternatively, resistance to radial compression (see paragraph [0048]).

In addition, Brown ‘848 describes adjusting the length of struts to vary the “compression resistance” in the “band-like elements”. Specifically, Brown ‘848 describes the stent illustrated by Figure 15 as having segments with “longer struts” that nevertheless exhibit “less compression resistance” than the shorter struts of the same stent (11:56-63). This passage teaches that the long-strut rings of Brown ‘848 will have lower radial strength (i.e. lesser compression resistance) than the short-strut rings. Put yet another way, the short-strut rings of Brown ‘848 will provide the radial strength for the Brown stent and therefore be less flexible than the long-strut rings. Thus, Brown ‘848 clearly identifies the length of a strut as the determinative factor (see 11:56-63).

In contrast, claim 6 recites that the second circumferential band (the high frequency rings) contribute to flexing (i.e. are more flexible than the first circumferential

band (the low frequency rings)). Brown describes a stent having the opposite properties. Moreover, as discussed above, paragraph [0051] of the present application specifically describes the benefit of having high frequency bands having struts of smaller width. Specifically, the greater number of loops per band combined with struts of a smaller width results in a lower maximal strain and increased flexibility to better conform to a curved lumen and bend with each beat of the heart, whereas one skilled in the art will recognize that the employment of low frequency bands to provide flexibility results in a higher maximal strain given the lower number of loops per band, resulting in a stent more likely to break upon repeated bending. Brown does not teach or suggest a stent having high frequency rings that contribute to the flexing of the stent, as claimed.

Therefore, claim 6 is patentable over the Brown '848 reference.

VII.D. Claim 6 is patentable pursuant to 35 U.S.C. § 103(a) in view of Brown '848

1. Claim 6 has been rejected as obvious on the basis that it allegedly would have been obvious to provide wider members 144 than members 120. Applicant respectfully disagrees with this rejection.

The Examiner apparently recognizes that Brown '848 does not teach or suggest struts of a first circumferential band that are wider than struts of a second circumferential band as recited by claim 6.

Whereas the present application recognizes the benefit of varying the <u>width</u> of struts to achieve either longitudinal flexibility or, conversely, resistance to radial compression (<u>see</u> paragraph [0048]), Brown '848 adjusts the <u>length</u> of struts to vary the

"compression resistance" in the "band-like elements" (see 11:56-63). Further, as discussed above, one skilled in the art would not contemplate adjusting the width of the struts in the stents described by Brown '848 given that Brown '848 teaches that long strut rings should have lesser resistance to radial compression. In other words, Brown '848 describes that long strut rings provide flexibility while the short strut rings provide radial strength, which is quite the opposite to that recited in claim 6. Moreover, as discussed above, paragraph [0051] of the present application specifically describes the benefit of having high frequency bands having struts of smaller width. Specifically, the greater number of loops per band combined with struts of a smaller width results in a lower maximal strain and increased flexibility to better conform to a curved lumen and bend with each beat of the heart, whereas one skilled in the art will recognize that the employment of low frequency bands to provide flexibility results in a higher maximal strain given the lower number of loops per band, resulting in a stent more likely to break upon repeated bending. Brown fails to recognize this structural feature of the stent.

Lastly, Brown '848 fails to teach or suggest a stent comprising a second circumferential band joined directly to adjacent first circumferential bands without intervening materials. The modification of the size of members 144 relative to members 120 does not cure this deficiency. Therefore, claim 6 is patentable over the Brown '848 reference.

VII.E. Claims 42-44 are patentable pursuant to 35 U.S.C. § 102(e) in view of Brown '848

1. Claims 42-44 are dependent on claim 1. Therefore, insofar as claim 1 is patentable under 35 U.S.C. § 102(e) in view of Brown '848 as discussed in section VII.A., supra, claims 42-44 likewise are patentable over the Brown '848 reference.

VII.F. Claims 42-44 are patentable pursuant to 35 U.S.C. § 103(a) in view of Brown '848

1. Claims 42-44 are dependent on claim 1. Therefore, insofar as claim 1 is patentable under 35 U.S.C. § 103(a) in view of Brown '848 as discussed in section VII.A., supra, claims 42-44 likewise are patentable over the Brown '848 reference.

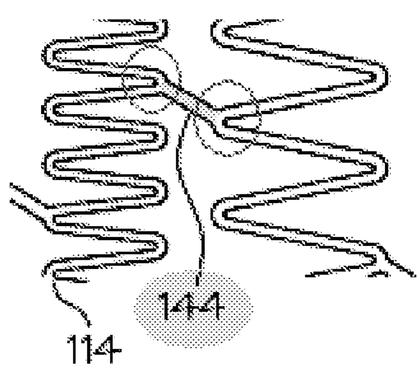
VII.G. Claim 49 is patentable pursuant to 35 U.S.C. § 103(a) in view of Brown '793 and Burpee

1. Claim 49 has been rejected as obvious pursuant to §103 over Brown '793 in view of Burpee on the basis that Brown '793 allegedly describes limitations recited in claim 49 with the exception of: (1) a first loop containing section having loops that are 180° out of phase with the loops of a second loop containing section, and (2) the first and second loop containing sections have struts that are wider than the struts of a third loop containing section, which is allegedly described by Burpee. Applicant respectfully disagrees with this rejection.

Claim 49 recites a stent consisting essentially of first, second and third loop containing sections wherein "at least one of said first and second loop containing sections" and every third loop containing section are "formed of a single, continuous,

generally sinusoidal pattern". Further, claim 49 requires that a third loop containing section be disposed between each of the first and second loop containing sections, and that each third loop containing section is alternately joined to the adjacent first and second loop containing sections. As is well understood, "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. In re Herz, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) (emphasis in original); see also MPEP §2111.03.

Brown's "interconnecting elements" materially alter the instant claimed structure. Brown '793 like Brown '848[3] describes a stent having "band-like elements" joined with intervening "interconnecting elements." Brown '793 describes the "interconnecting elements" as "having first ends and second ends" that "extend from adjacent band like elements" (2:45-49). The interconnecting elements connect adjacent bands at "circumferentially offset and ... longitudinally offset" ends (2:31-33, 6:60-63), as shown in Figure 2 as follows:



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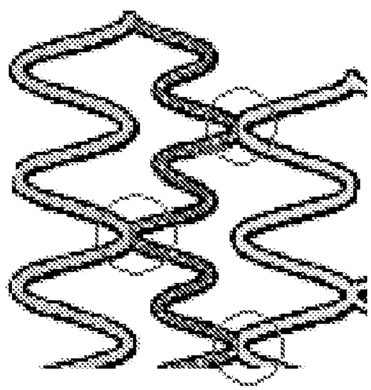
[3] Brown '793 reference contains the identical subject matter as the Brown '848 reference. These are patents related as continuation applications.

Because the ends of the interconnecting elements attach to the adjacent band-like elements at circumferentially and longitudinally offset points (circled in red), the adjacent band-like elements must be arranged such that the peak and trough of each are also offset. By contrast, the third loop containing section recited by claim 49 is joined to the first and second loop containing sections, requiring that the "peaks" and "troughs" of the adjacent loop containing sections be aligned with one another to connect, as shown below in Figure 3.



Clearly, the points of connection (circled in red) between the third loop containing section (red) and the adjacent first and second loop containing sections (blue and green) must be circumferentially and longitudinally aligned. This arrangement is required to maintain the out-of-phase orientation of the low frequency rings, as recited in the claims, and to maintain a stent structure that does not have loop peaks directly abutting one another. Thus, the introduction of an interconnecting element as described in the Brown '793 reference requires a material alteration to the stent recited by claim 49 and as taught by the present application. Because Brown '793 does not teach or suggest a stent consisting essentially of third loop containing sections joined to adjacent

first and second loop containing sections, Brown '793 does not meet every limitation of claim 49.

The addition of Burpee does not remedy this deficiency of Brown '793. Burpee describes a stent comprising "circumferential sets of strut members" connected either by "'S' shaped undulating longitudinals" or "straight links" (3:41-43), as shown in Figure 3 of Burpee as follows:

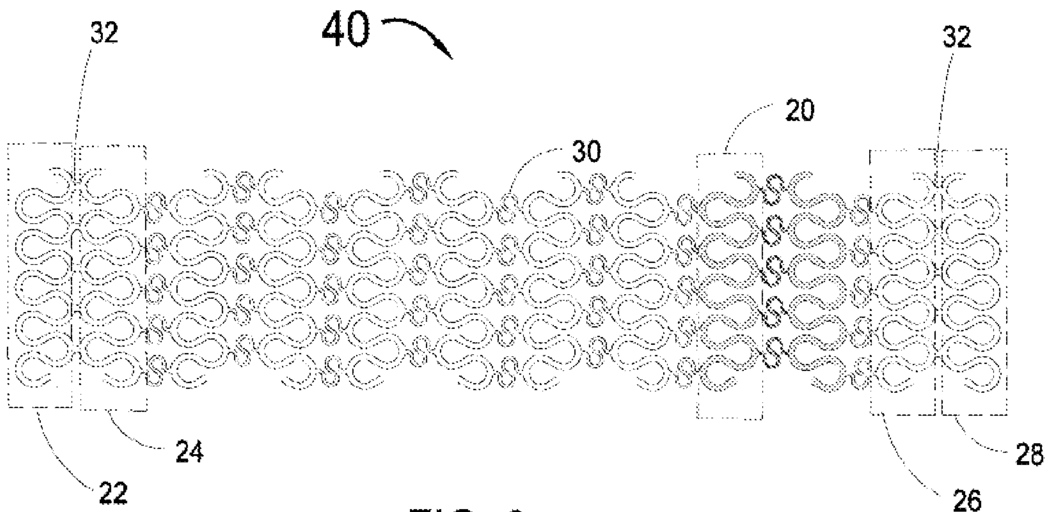


FIG. 3

Thus, the "circumferential sets" (blue) are connected to each other by "undulating longitudinals" (red) in a manner similar to the "interconnecting members" that connect adjacent "band-like elements" as described in Brown '793. Neither Burpee nor Brown '793, alone or in combination, teach or suggest a stent consisting essentially of first or second loop containing section formed of a single, continuous, generally sinusoidal pattern adjacent and connected to a third loop containing section formed of a single, continuous, generally sinusoidal pattern.

Furthermore, altering the width of the struts of Brown '793 to reach claim 49 is not an obvious modification. As discussed above with reference to Brown '848, Brown

‘793 describes functional significance of having stent struts of different lengths. Whereas the present application recognizes the inventive benefit of varying the width of struts to achieve either longitudinal flexibility or, alternatively, resistance to radial compression (see paragraph [0048]), Brown ‘793 relies on adjusting the length of struts to vary the “compression resistance” in the “band-like elements”. Further, as discussed above, one skilled in the art would not contemplate adjusting the width of the struts in the stents described by Brown ‘793 given that Brown ‘793 specifically describes adjusting strut length to modify radial strength; i.e., long-strut rings have “less compression resistance”. Moreover, as discussed above, paragraph [0051] of the present application specifically describes the benefit of having high frequency bands having struts of smaller width. Specifically, the greater number of loops per band combined with struts of a smaller width results in a lower maximal strain and increased flexibility to better conform to a curved lumen and bend with each beat of the heart, whereas one skilled in the art will recognize that the employment of low frequency bands to provide flexibility results in a higher maximal strain given the lower number of loops per band, resulting in a stent more likely to break upon repeated bending.

Lastly, Burpee’s description of the width of the “undulating longitudinal structures” is irrelevant to Brown ‘793 in that Brown ‘793 does not describe any similar structure. Indeed, there is no reason why one skilled in the art would alter the width of the rings of Brown ‘793 to reach the claimed invention. Therefore, there is no common sense reason to modify Brown ‘793 to reach the claimed invention.

Therefore, claim 49 is patentable over the Brown ‘793 reference in view of the Burpee reference.

VIII. Claims Appendix

Claim 1. A coronary stent having a longitudinal axis along the length of the stent comprising:

a. a first loop containing section having loops, said first loop containing section having an axis orthogonal to the longitudinal axis of the stent, the loops in said first loop containing section occurring at a first frequency;

b. a second loop containing section having loops, said second loop containing section having an axis orthogonal to the longitudinal axis of the stent, the loops in said second loop containing section also occurring at said first frequency;

c. said first and second loop containing sections each form a single, continuous, generally sinusoidal pattern around the entire circumference of the stent; and

d. a third loop containing section, said third loop containing section formed of a single, continuous, generally sinusoidal pattern also having an axis orthogonal to the longitudinal axis of the stent, the loops in said third loop containing section occurring at a second frequency that is higher than said first frequency, said third loop containing section disposed in the general circumferential space between each of said first and second loop containing sections to form consecutive repeating patterns along the longitudinal axis of the stent for at least two repetitions and alternately joined to said first and second loop containing sections directly without any intervening material forming a uniform pattern of flexible cells;

e. the loops in said first, second and third loop containing sections being disposed and adapted to cooperate so that, components of said third loop containing section contribute to the cell's elongating or shortening when the stent is flexed; and

f. the loops of the first, second, and third loop containing sections further include struts having a thickness in the radial direction and width in the circumferential direction, wherein the struts of the first and second loop containing sections are wider than the width of the struts of the third loop containing section.

Claim 2. (canceled)

Claim 3. (canceled)

Claim 4. (canceled)

Claim 5. (canceled)

Claim 6. A coronary stent comprising:

a. a first circumferential band, formed of a single, continuous, generally sinusoidal pattern of loops at a first frequency having a single axis extending around the entire circumference of the stent;

b. a second circumferential band, formed of a single, continuous, generally sinusoidal pattern of loops, said second band having an axis parallel to the axis of the first band, and said loops occurring at a second frequency higher than said first frequency, said second circumferential band extending in a continuous pattern of loops around the entire circumference of the stent, said first circumferential band alternating with said second circumferential band to form consecutive patterns along the

longitudinal axis of the stent for at least two repetitions, said second bands periodically coupled to said first bands directly without any intervening material to form cells;

c. patterns of loops in said bands being disposed and adapted to cooperate so that second circumferential bands contribute more than first circumferential bands to deformation during flexing of the stent; and

d. the loops of the first, and second bands further include struts having a thickness in the radial direction and width in the circumferential direction, wherein the struts of the first bands are wider than the width of the struts of the second bands.

Claim 7. (canceled)

Claim 8. (canceled)

Claim 9. (canceled)

Claim 10. (canceled)

Claim 11. (canceled)

Claim 12. (canceled)

Claim 13. (canceled)

Claim 14. (canceled)

Claim 15. (canceled)

Claim 16. (canceled)

Claim 17. (canceled)

Claim 18. (canceled)

Claim 19. (canceled)

Claim 20. (canceled)

Claim 21. (canceled)

Claim 22. (canceled)

Claim 23. (canceled)

Claim 24. (canceled)

Claim 25. (canceled)

Claim 26. (canceled)

Claim 27 (canceled)

Claim 28. (canceled)

Claim 29. (canceled)

Claim 30. (canceled)

Claim 31. (canceled)

Claim 32. (canceled)

Claim 33. (canceled)

Claim 34. (canceled)

Claim 35. (canceled)

Claim 36. (canceled)

Claim 37. (canceled)

Claim 38. (canceled)

Claim 39. (canceled)

Claim 40. (canceled)

Claim 41. (canceled)

Claim 42. A stent according to claim 1, wherein the loops in the first loop containing sections are all in phase.

Claim 43. A stent according to claim 1, wherein, upon expansion, the cells on the outside of a curved section of the stent narrows as the cells elongate, and cells inside of a curve widen as the cells shorten.

Claim 44. A stent according to claim 6, wherein, upon expansion, the cells on the outside of a curved section of the stent narrows as the cells elongate, and cells inside of a curve widen as the cells shorten.

Claim 45. (canceled)

Claim 46. (canceled)

Claim 47. (canceled)

Claim 48. (canceled)

Claim 49. A coronary stent having a longitudinal axis along the length of the stent consisting essentially of in both the unexpanded and expanded state:

a. a first loop containing section, said first loop containing section having an axis perpendicular to the longitudinal axis of the stent, the loops in said first loop containing section occurring at a first frequency;

b. a second loop containing section, said second loop containing section having an axis perpendicular to the longitudinal axis of the stent, the loops in said second loop containing section also occurring at said first frequency, said second loop containing section being 180° out of phase with said first loop containing section along the longitudinal axis of the stent;

c. at least one of said first and second loop containing sections formed of a single, continuous, generally sinusoidal pattern; and

d. a third loop containing section, said third loop containing section formed of a single, continuous, generally sinusoidal pattern extending in a continuous band of loops around the entire circumference of the stent, the loops in said third loop containing section occurring at a second frequency that is higher than said first frequency, said loops in said third loop containing section having an axis parallel to the axis of the first and second loop containing sections, said third loop containing section disposed in the generally circumferential space between each of said first and second loop containing sections to form consecutively repeating patterns along the longitudinal axis of the stent for at least two repetitions and alternately joined to said first and second loop containing sections, said first, second and third loop containing sections forming a pattern of uniform cells; and

e. the loops of the first, second, and third loop containing sections further include struts having a thickness in the radial direction and width in the circumferential direction, wherein the struts of the first and second loop containing sections are wider than the struts of the third loop containing section.

Claim 50. (canceled)

Claim 51. (canceled)

IX. Evidence Appendix

Applicants attach copies of the following documents cited above:

IX.A. Final Office Action dated May 12, 2009

IX.B Published United States Patent Application No. 2002/0022876 A1 (Richter et al.)

IX.C United States Patent No. 6,776,793 B2 (Brown et al.)

IX.D United States Patent No. 7,204,848 B1 (Brown et al.)

IX.E United States Patent No. 6,179,868 B1 (Burpee et al.)

IX.F United States Patent No. 6,120,847 (Yang et al.)

X. Related Proceedings Index

Applicants attach copies of the following decisions rendered by the Board in the proceedings identified pursuant to 37 C.F.R. 41.37(c)(1)(ii) above:

X.A. Notice of Panel Decision from Pre-Appeal Brief Review issued on August 5, 2009, United States Patent Application No. 11/395,751

AUTHORIZATION

The Commissioner is hereby authorized to charge any additional fees which may be required for consideration of this Amendment to Deposit Account No. 50-4387, Order No. 92077.003.

In the event that an extension of time is required, or which may be required in addition to that requested in a petition for an extension of time, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to Deposit Account No. 50-4387, Order No. 92077.003.

Respectfully submitted,
Cadwalader, Wickersham & Taft LLP

Dated: December 9, 2009

By: Dorothy R. Auth

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